



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-0002

September 29, 2014

ImaCor, Inc.  
% Mr. James W. Monroe  
Director of QA/RA  
839 Stewart Avenue, Suite 3  
GARDEN CITY NY 11530

Re: K142054  
Trade/Device Name: Zura-EVO Imaging System  
Regulation Number: 21 CFR 892.1550  
Regulation Name: Ultrasonic pulsed doppler imaging system  
Regulatory Class: II  
Product Code: IYN, IYO, ITX  
Dated: July 30, 2014  
Received: July 31, 2014

Dear Mr. Monroe:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

This determination of substantial equivalence applies to the following transducers intended for use with the Zura-EVO Imaging System, as described in your premarket notification:

Transducer Model Number

ClariTEE Probe

TTE probe SA4-2/24

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Janine M. Morris", is written over a large, light gray, semi-transparent watermark of the FDA logo.

for

Janine M. Morris  
Director  
Division of Radiological Health  
Office of In Vitro Diagnostics  
and Radiological Health  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)  
K142054

Device Name  
Zura-EVO Imaging System

### Indications for Use (Describe)

1. The Zura-EVO System is intended for the following applications: Cardiac and , Transesophageal. Measurement and calculation packages that provide information of anatomical structures that may be used by a physician for clinical diagnosis purposes.
2. When used with the ClariTEE probe -- The episodic assessment of cardiac function using transesophageal echocardiography (TEE). It is indicated for use in clinical settings including long term settings such as the ICU for an indwelling time not to exceed 72 hrs.
3. When used with the TTE probe is intended for imaging and assessment of Cardiac anatomy and function

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

### FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
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*“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”*

### Zura-EVO Imaging System

**Intended Use:** When used with the ClariTEE probe -- The episodic assessment of cardiac function using transesophageal echocardiography (TEE). It is indicated for use in clinical settings including long term settings such as the ICU for an indwelling time not to exceed 72 hrs. When used with the SA4-2/24 Phased Array Transducer (TTE Probe) it is intended for Diagnostic Ultrasound imaging or fluid analysis of the human body as follows:

Clinical Application	Probe	Mode of Operation							
		B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes	Other (Notes)
Opthalmic									
Fetal									
Abdominal									
Intraoperative <sup>1</sup>									
Intraoperative Neurological									
Pediatric									
Small Organ <sup>2</sup>									
Neonatal Cephalic									
Adult Cephalic									
Cardiac	<b>SA4-2/24 Phased Array Transducer (TTE Probe)</b>	N				N			
Transesophageal	ClariTEE Probe	P				P			
Transrectal									
Transvaginal									
Transurethral									
Transcranial									
Peripheral Vascular									
Laparoscopic									
MSK Conventional									
MSK Superficial									
Vascular Access									
Nerve Block									
Other									

N = New Indication; P = Previously cleared under K080223, K100989

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(Division Sign-off)  
Division of Radiological Devices  
Office of In Vitro Diagnostic Device  
Evaluation and Safety  
510K

# DIAGNOSTIC ULTRASOUND INDICATION FOR USE FORM

## ClariTEE Probe

Intended Use: When used with the ClariTEE probe -- The episodic assessment of cardiac function using transesophageal echocardiography (TEE). It is indicated for use in clinical settings including long term settings such as the ICU for an indwelling time not to exceed 72 hrs.

Clinical Application	Mode of Operation							
	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes	Other (Notes)
Opthalmic								
Fetal								
Abdominal								
Intraoperative <sup>1</sup>								
Intraoperative Neurological								
Pediatric								
Small Organ <sup>2</sup>								
Neonatal Cephalic								
Adult Cephalic								
Cardiac								
Transesophageal	P				P			
Transrectal								
Transvaginal								
Transurethral								
Transcranial								
Peripheral Vascular								
Laparoscopic								
MSK Conventional								
MSK Superficial								
Vascular Access								
Nerve Block								
Other								

N = New Indication; P = Previously cleared under K080223, K100989

**DIAGNOSTIC ULTRASOUND INDICATION FOR USE FORM**

**SA4-2/24 Phased Array Transducer (TTE Probe)**

Intended Use: Diagnostic Ultrasound imaging or fluid analysis of the human body as follows:

Clinical Application	Mode of Operation							
	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes	Other (Notes)
Ophthalmic								
Fetal								
Abdominal								
Intraoperative <sup>1</sup>								
Intraoperative Neurological								
Pediatric								
Small Organ <sup>2</sup>								
Neonatal Cephalic								
Adult Cephalic								
Cardiac	N				N			
Transesophageal								
Transrectal								
Transvaginal								
Transurethral								
Transcranial								
Peripheral Vascular								
Laparoscopic								
MSK Conventional								
MSK Superficial								
Vascular Access								
Nerve Block								
Other								

N = New Indication; P = Previously cleared under K080223, K100989

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(Division Sign-off)  
Division of Radiological Devices  
Office of In Vitro Diagnostic Device  
Evaluation and Safety  
510K K\_\_\_\_\_

## **5. 510(K) Summary**

### **510(K) SUMMARY**

#### **Zura-EVO Imaging System**

#### **Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared:**

ImaCor Inc  
839 Stewart Ave  
Unit 3  
Garden City, NY 11530  
Phone: (732) 718-9199, Facsimile: (516) 393-0969  
Contact Person: James W. Monroe; jmonroe@imacorinc.com, 732-718-9199

Date Prepared: July 24, 2014

#### **Name of Device and Name/Address of Sponsor**

##### **Zura-EVO Imaging System**

ImaCor Inc  
839 Stewart Ave  
Unit 3  
Garden City, NY 11530

#### **Common or Usual Name**

Ultrasound Imaging System

#### **Classification Name**

Ultrasonic Pulsed Doppler Imaging System (892.1550) Ultrasonic Pulsed Echo Imaging System (892.1560) with a Diagnostic Ultrasonic Transducer (892.1570)

#### **Product Codes**

IYO, IYN, ITX,

#### **Device Class**

II

#### **Predicate Devices**

ImaCor Zura K080223, K100989  
Ultrasonix SonixTablet K102997

## Intended Use / Indications for Use

1. The Zura-EVO Imaging System is intended for the following applications: Cardiac and , Transesophageal. Measurement and calculation packages that provide information of anatomical structures that may be used by a physician for clinical diagnosis purposes.
2. When used with the ClariTEE probe -- The episodic assessment of cardiac function using transesophageal echocardiography (TEE). It is indicated for use in clinical settings including long term settings such as the ICU for an indwelling time not to exceed 72 hrs.
3. When used with the TTE probe is intended for imaging and assessment of Cardiac anatomy and function

## Device Description

The Zura-EVO Imaging System is a multi-purpose mobile, software controlled diagnostic ultrasound system. Its function is to acquire ultrasound echo data and display it in B-Mode, or Color Doppler Mode on a Flat Panel Display. The user interface includes specialized controls, a minimized computer keyboard, and touch panel on an ergonomic console.

The system has an optional electrocardiography (ECG) display feature and support for a 3-lead ECG cable assembly. The systems provide measurement capabilities for anatomical structures that provide information used for clinical diagnostic purposes. The system has measurements and calculations, image storage and review, and recording capabilities. The systems include a Digital Imaging and Communications (DICOM) module which enables storage.

The Zura-EVO Imaging System consists of the following major components:

1. **Ultrasound Machine:** A predicate device ultrasound machine (K102997)
2. **Ultrasound Probes**
  - a. **ClariTEE Probe:** A miniaturized TEE probe optimized for longer dwell time relative to standard TEE probes that enables long term use in clinical settings such as the ICU. This probe has predicate coverage under K080223 and K100969.
  - b. **TTE probe SA4-2/24:** Transthoracic probe has a predicate coverage under K102997
3. **Ultrasound Imaging Software:** Ultrasound imaging functions are controlled via the ImaCor Zura software. The Graphical User Interface, which is the piece of software exposed to the user, communicates user inputs to the Ultrasound Imaging Platform which interfaces with the Ultrasound Transducer. The ImaCor Zura

software also communicates with the probe directly to monitor the probe's lifespan. Orientation and position of the probe is controlled manually by the user.

### **Description of design modifications**

The Zura-EVO is different from the original Zura design in that the EVO GUI is via a touch display screen. A miniaturized keyboard and mouse are provided but are optional. The EVO mains power supply includes a battery so that the machine does not need to be rebooted when moving from bedside to bedside in a critical care setting.

Finally, while the Zura is provided only with the 72 hr. miniaturized ClariTEE probe (ultrasound transducer). The EVO is provided with two transducers; the 72 hr. ClariTEE probe and an optional TTE probe.

The software controls standard ultrasound machine functions such as imaging, recording and measuring. Continuous imaging is limited by a 20 minute software interlock should the operator mistakenly leave the machine in continuous imaging mode, thus limiting the potential unintentional exposure of the patient's mucosal tissue to acoustic energy. Maximum probe face temperature is limited according to FDA consensus standard IEC 60601-2-37.

There are two modes of imaging; type B and color flow Doppler.

### **Non-Clinical Testing**

The following non-clinical testing was conducted: electrical safety to meet the requirements of IEC 60601 3<sup>rd</sup> Edition, Sterility to demonstrate and SAL  $10^{-6}$ , aged acceleration testing, and acoustic output testing to meet the requirements of IEC 60601-2-37.

### **Comparison to Predicate Device**

The Zura-EVO Ultrasound Scanner is substantially equivalent to the predicate devices listed below with respect to intended use/indications for use, principles of operation and technological characteristics.

The Zura-EVO Ultrasound Scanner includes a digital beam-former that is identical in function to the predicate devices beam-former. It allows transmitting and receiving signals through the ultrasound transducers. The ultrasound transducers are identical to the ones used on predicate devices.

The backend processing is also similar to the predicate devices and yields an ultrasound image in realtime for diagnosis purposes.

**Table of FDA Consensus Standards**

Guidance ( guidance document section ref.)	Design Characteristic	FDA Consensus Standard	Recognition Number
	Risk Assessment	ISO 14971:2007 Medical devices - Application of risk management to medical devices	5-40
	Acoustic Output (Track 1)	EN 60601-2-37:2008 Medical electrical equipment -- Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment	
	Thermal Mechanical and Electrical Safety	EN 60601-1:2006 Medical electrical equipment -- Part 1: General requirements for safety  EN 60601-2-37:2008 Medical electrical equipment -- Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment	5-77  5-53
	Patient Contacting Materials	Biological evaluation of medical devices	
		EN ISO 10993-1 2009	2-179
		EN ISO 10993-5 2009	2-153

		EN ISO 10993-6 2009 EN ISO 10993-7 2007	2-120 14-335
		EN ISO 10993-10 2010	2-173
		EN ISO 10993-11 2009	2-176
		EN ISO 10993-12 2012	2-191
	Cleaning Disinfection, Sterilization and Pyrogenicity	EN ISO 11135-1:2007  Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 11135-1:2007)	14-228
	Software/Firmware	EN 62304  Medical Device Software – Software Life Cycle Processes	13-32
	Labeling		
	EMC	EN 60601-1-2:2007  Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests	5-53

## Substantial Equivalence

The new device (EVO) has significant predicate coverage

	<b>Zura –EVO Subject Device</b>	<b>Zura with ClariTEE Probe (K080223, K100989)</b>	<b>Ultrasonix Sonix-Tablet K102997</b>
<b>Intended Use</b>	<p>Intended for the following applications: Cardiac and , Transesophageal. Measurement and calculation packages that provide information of anatomical structures that may be used by a physician for clinical diagnosis purposes.</p> <p>2. When used with the ClariTEE probe -- The episodic assessment of cardiac function using transesophageal echocardiography (TEE). It is indicated for use in clinical settings including long term settings such as the ICU for an indwelling time not to exceed 72 hrs.</p> <p>3. When used with the TTE probe is intended for imaging and assessment of Cardiac anatomy and function</p> <p>Diagnostic ultrasound imaging multimodality includes TEE, TTM, Linear</p>	<p>Intended for use in the episodic assessment of cardiac function using transesophageal echocardiography. It is indicated for use in clinical settings, including long-term settings such as the ICU, for an indwelling time period not to exceed 72 hours. The ImaCor</p> <p>Diagnostic ultrasound imaging - TEE</p>	<p>Intended for the following applications: Abdominal, Cardiac, I ntraolperative Neurological, Fetal, Pediatric, Small Parts, Neonatal/ Adult Cephalic, OB/GYN, Transesophageal, Transrectal,Transvaginal, Peripheral Vascular, Musculoskeletal conventional, Musculoskeletal superficial, Pelvic, Nerve Block, Vascular Access, Transcranial. The system also provides the ability to measure anatomical structures {fetal, abdominal, pediatric, small organ, cardiac, transrectal, transvaginal, peripheral vessel, musculoskeletal} and provides calculation packages that provide information to the clinician that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.</p> <p>Diagnostic ultrasound imaging multimodality includes TEE, TTM, Linear</p>
<b>User Population</b>	All except pediatric for TEE	All except pediatric for TEE	All
<b>Technological Characteristics</b>	<p>Ultrasound diagnostic with miniaturized TEE, TTE, Linear</p> <p>Software controls type B mode imaging and color flow doppler</p>	<p>Ultrasound diagnostic with miniaturized TEE probe</p> <p>Software controls type B mode imaging and color flow doppler</p>	<p>Ultrasound diagnostic with miniaturized probe/transducer</p> <p>Software controls type B mode imaging and color flow doppler</p>
<b>Major System Components</b>	<p>Ultrasound machine containing beam-forming architecture</p> <p>Disposable single use probe (miniaturized)</p> <p>Effective diameter of 5.5 mm.</p> <p>Phased array transducer.</p> <p>Detachable handle</p> <p>Software</p> <p>Quantitative software aids</p> <p>TTE and Linear probe</p>	<p>Ultrasound machine containing beam-forming architecture</p> <p>Disposable single use probe (miniaturized)</p> <p>Effective diameter of 5.5 mm.</p> <p>Phased array transducer.</p> <p>Detachable handle</p> <p>Software</p> <p>Quantitative software aids</p>	<p>Ultrasound machine containing beam-forming architecture</p> <p>Disposable single use probe (miniaturized)</p> <p>Effective diameter of 5.5 mm.</p> <p>Phased array transducer.</p> <p>Detachable handle</p> <p>Software</p> <p>Quantitative software aids</p> <p>Transducer list includes identical TTE, Linear probe</p>

<b>Power Source</b>	Nominal 120 Vac, 50/60 hz, single phase	Nominal 120 Vac, 50/60 hz, single phase	Nominal 120 Vac, 50/60 hz, single phase
<b>Biocompatibility</b>	ISO 10993	ISO 10993	ISO 10993
<b>Software</b>	Moderate Concern	Moderate Concern	Moderate Concern
<b>Sterilization</b>	ETO; disposable TEE probe provided sterile  Other probes – standard disinfection	ETO; disposable probe provided sterile	Reusable, standard disinfectant procedure applied
<b>Acoustic Output</b>	Acoustic Output Track 1 device	Acoustic Output Track 1 device	Acoustic Output Track 3 device
<b>Accessory</b>	Three lead ECG (not for diagnostic purposes)	Three lead ECG (not for diagnostic purposes)	Three lead ECG (not for diagnostic purposes)

1. The ImaCor EVO is substantially equivalent to the ImaCor Zura and ClariTEE probe cleared for marketing by the FDA under K080223 and K100989. These 510K coverages are for the ImaCor ClariTEE probe

2. The EVO is substantially equivalent to the Sonix-Tablet, manufactured by Ultrasonix Medical Corporation and cleared for marketing by the FDA under K102997. Ultrasonix is the OEM for the EVO and the Sonix-Tablet is the EVO's twin. The Linear and TTE transducers provided with the EVO are covered with the Sonix-Tablet under K102997